

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 22-45 are pending. Elected claim 21 is canceled and replaced by claims 38-45. Nonelected claims 1-20 were withdrawn from consideration by the Examiner; Applicants cancel the nonelected claims without prejudice to future prosecution of their subject matter.

The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. The brief description of the drawings is amended to refer to Figs. 1A-1B. Support for the new claims may be found, inter alia, at page 10-12 of the specification where antibodies and their production (including raising and selecting them) are described. But if the Examiner should disagree and allege that entry of the new claims adds new matter, he is respectfully requested to point out the challenged limitation with particularity in the next Action so additional support may be cited in response.

The first paragraph on page 1 containing a priority claim to the parent application is amended to refer to the issued patent. The parent U.S. applications are listed therein. The declaration/oath was objected to because it does not list the serial numbers of the parent U.S. applications. The undersigned contacted the Examiner by telephone and confirmed with him that the serial number of the foreign priority document was listed in the declaration/oath. A certified copy of the foreign priority document was submitted in the parent application. Submission of another copy is not required and acknowledgment that it was received in the parent application is requested.

The present application is a division of Appln. No. 09/545,002, which is a division of Appln. No. 08/969,125. The declaration/oath submitted on September 29, 2003 in this application is a copy of the declaration/oath accepted in the parent applications. Under 37 CFR § 1.63 (d)(1), a newly executed declaration/oath is not required. This is a continuing application under 37 CFR § 1.53(b) and a copy of the declaration/ oath accepted in a parent application is sufficient according to 37 CFR § 1.63(d)(1)(iv). Because the reference to parent U.S. applications is satisfied by their listing in the first paragraph of

the specification, the declaration/oath is not required to list serial numbers of the parent U.S. applications. Withdrawal of the objections is requested.

35 U.S.C. 101 – Utility

Claim 22 was rejected under Section 101 because they are allegedly “directed to non-statutory subject matter.” Applicants traverse because the claim is amended in accordance with the Examiner’s suggestion.

Withdrawal of the Section 101 rejection is requested.

35 U.S.C. 112 – Definiteness

Claims 21-22 were rejected under Section 112, second paragraph, as being allegedly “indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Applicants traverse.

Claim 21 is replaced by method claims 38-45 which recite active, positive steps in accordance with the Examiner’s suggestion.

The phrase “synthetic construct” is deleted from claim 22 because this limitation is not required for patentability. Instead, it is replaced by scFv molecules, chimeric molecules (e.g., humanized antibody), and molecules comprising an additional moiety (e.g., label or pharmaceutically active agent) in new dependent claims (see pages 11-12 of the specification).

Applicants request withdrawal of the Section 112, second paragraph, rejections because the pending claims are clear and definite.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claim 22 was rejected under Section 102(e) as allegedly anticipated by Wilson et al. (U.S. Patent 6,911,530). Applicants traverse because the claimed antibodies, antibody fragments, and synthetic constructs are directed to those which preferably “bind specifically to polypeptides of the present invention” (see page 10, lines 8-9, of the specification).

Wilson et al. do not disclose antibodies which are specific for the polypeptide of SEQ ID NO:9 or the polypeptide of SEQ ID NO:9 with the two mutations Thr130Ile and Gly358Asp. The polyclonal antibody of the cited reference was raised in Example 13 against murine IL-13R α (NR4 or SEQ ID NO:2 in Wilson et al.) instead of human IL-13R α (SEQ ID NO:4 in Wilson et al.). As noted by the Examiner on page 5 of the Action, the human and murine polypeptides are only a 72.9% match. Thus, Applicants’ antibody and the antibody of Wilson et al. necessarily bind to polypeptides of different amino acid sequences. Their specificities are similarly distinct. Applicants submit that this feature of their claimed invention is sufficient to distinguish over the cited reference so any other incorrect allegations about its disclosure are not disputed here, but the opportunity to dispute them in the future is reserved.

Withdrawal of the Section 102 rejection is requested because the cited reference fails to disclose all limitations of the claimed invention.

35 U.S.C. 103 – Nonobviousness

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. A determination of prima facie obviousness requires a reasonable expectation of success. See *In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

Claim 22 was rejected under Section 103(a) as allegedly unpatentable over Aman (J. Biol. Chem. 271:29265-29270, 1996) in view of Takatsu et al. (U.S. Patent 5,453,491). Applicants traverse because no antibody specific for human IL13R α was disclosed in the cited references and its production would not have been suggested.

It was admitted on page 12 of the Action that Amon does not disclose antibodies. Takatsu et al. only disclose production of antibodies to IL5. For the sake of argument,

even if both references were taken together, they do not show a reasonable expectation of success of making antibodies, antibody fragments, and synthetic constructs specific for the polypeptide of SEQ ID NO:9 or the polypeptide of SEQ ID NO:9 with mutations Thr130Ile and Gly358Asp in accordance with Applicants' claimed invention.

Claim 22 was also rejected under Section 103(a) as allegedly unpatentable over Hilton (Proc. Natl. Acad. Sci. USA 93:497-501) in view of Aman and further in view of Takatsu et al. (U.S. Patent 5,453,491). Applicants traverse because no antibody specific for human IL13R α was disclosed in the cited references and its production would not have been suggested.

Hilton discloses a mouse amino acid sequence for IL13R α . Its disclosure would lead away from Applicants' invention of antibodies, antibody fragments, and synthetic constructs specific for human IL13R α . And it certainly does not remedy the failure of Aman and Takatsu et al. to show a reasonable expectation of success of making antibodies, antibody fragments, and synthetic constructs specific for the polypeptide of SEQ ID NO:9 or the polypeptide of SEQ ID NO:9 with mutations Thr130Ile and Gly358Asp in accordance with Applicants' claimed invention.

Applicants submit that this feature of their claimed invention is sufficient to distinguish over the cited references so any other incorrect allegations about their disclosures are not disputed here, but the opportunity to dispute them in the future is reserved.

Withdrawal of the Section 103 rejections is requested because Applicants' claimed invention would not have been obvious to the ordinarily skilled artisan at the time they made their invention.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

Gary R. Tanigawa
Reg. No. 43,180

901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100